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10/522,320	10/17/2005	John L. Schenk	XY-Optimum-USNP	6962

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EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
06/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/522,320	SCHENK ET AL.	
	Examiner	Art Unit	
	TIFFANY M. GOUGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-12,15,16,18,21,54,150,151 and 155* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-12,15,16,18,21,54,150,151 and 155* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed 3/22/2010 has been received and entered into the case. Claims 1, 5-12, 15, 16, 18, 21, 150,151, 154, 155 are pending and have been considered on the merits. All arguments and amendments have been considered. The Examiner would like to direct applicants attention to the Interview Summary mailed 6/10/2010. Its content discloses an interview conducted between applicants representative Mr. Craig Miles and the Examiner regarding applicants attempt to overcome the Seidel and Lindsey references of record. Mr. Miles was informed that the priority document relied upon to overcome the references of record does not have support for the amended claims. Thus, as discussed below, at present, the Seidel and Lindsey references cannot be overcome by applicants arguments.

New rejections necessitated by amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 and dependent claims 5-12, 15, 16, 18, 21, 150,151, 154, 155 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the amendment to claim 1 which introduces "…at a temperature between **above** 5°C and about 25°C… staining …**at temperature above the temperature at which sperm cells transition from a liquid phase to a gel phase**…" is not described in the specification as originally filed. Applicant teach incubating at temperatures between **about** 5°C and about 25°C and staining **at 34°C** for either 30 or 60 minutes. It is not clear and there is no support for staining at any other temperature above the temperature at which sperm cell membranes lipids transition from liquid to gel phase. Therefore, the amendments change the scope of the claims and applicants invention for which no support is provided. **This is a new matter rejection.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 9-12, 15, 16, 18, 21,150 are rejected under 35 U.S.C. 102(a) as being anticipated by Lindsey et al. (Equine Vet. Journal, March, 2002, p.128-132).

Lindsey teaches a method of separating sperm cells comprising incubating the semen at temperatures between 20-25°C, staining with Hoecsht 33342 for about 50 minutes at 34°C and separating sperm cells based upon sex characteristics (p.129, 2nd column-p.130 1st column). Lindsey teaches transporting semen, adding an antibacterial, i.e. E-Z Mixin CST, which contains Amikacin antibiotic, extending the semen, removing seminal plasma and sorting using a flow cytometer (p.129, 2nd column-p.130 1st column).

Thus, the reference anticipates the claimed invention.

Claims 1, 5, 6, 9-12, 15, 16, 18, 21,150 are rejected under 35 U.S.C. 102(a) as being anticipated by Lindsey et al. (Equine Vet. Journal, March, 2002, p. 121-127).

Lindsey teaches a method of separating sperm cells comprising incubating the semen at temperatures between 20-25°C, i.e. ambient temperatures, staining with Hoecsht 33342 for about 50 minutes at 34°C and separating sperm cells based upon sex characteristics (p.123, semen collection and processing-treatment 4). Lindsey teaches transporting semen, adding an antibacterial, extending the semen, removing seminal plasma and sorting using a flow cytometer (p.123, semen collection and processing-treatment 4).

Thus, the reference anticipates the claimed invention.

Claims 1, 5, 6, 9-12, 15, 16, 18, 21,150 are rejected under 35 U.S.C. 102(b) as being anticipated by Buchanan et al. (Theriogenology, vol. 53, p.1333-1344, 2000).

Buchanan teaches a method of separating sperm cells comprising incubating the semen at temperatures between 20-25°C, i.e. ambient temperatures, staining with Hoecsht 33342 for about 50 minutes at 34°C and separating sperm cells based upon sex characteristics (abstract, p.1336-1337, Semen collection and processing). Buchanan teaches transporting semen, adding an antibacterial, extending the semen, removing seminal plasma and sorting using a flow cytometer (abstract, p.1336-1337, Semen collection and processing).

Thus, the reference anticipates the claimed invention.

Claims 1, 5, 6, 9-12, 15, 16, 18, 21,150 are rejected under 35 U.S.C. 102(b) as being anticipated WO00/06193.

WO'193 teaches a method of separating sperm cells comprising incubating the semen at temperatures between 20-25°C, i.e. ambient temperatures, staining with Hoecsht 33342 for about 50 minutes at 34°C and separating sperm cells based upon sex characteristics (p.10, lines 6-19, p. 36, lines 10-p.37, lines 1-10). WP'193 teaches transporting semen, adding an antibacterial, extending the semen, removing seminal plasma and sorting using a flow cytometer (p.10, lines 6-19, lines 10-p.37, lines 1-10).

Thus, the reference anticipates the claimed invention.

Maintained rejections of record

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-12, 15, 16, 18, 21,151,154, 155 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of WO 02/41906 A2 and WO 01/37655 A1 in view of each of Tardif et al. (Journal of Andrology, 1998) and Ellington (US 6140121) supported by Padilla et al (Journal of Animal Science, 1991), Johnson (Reprod. Fert. Dev., 1995) and Seidel et al., (Reproduction, 2002).

WO'906 teaches a method of separating sperm cells comprising obtaining a semen sample from a male mammal, particularly a bovine or equine mammal (p.9, lines 11-18), incubating the semen sample at temperatures ranging from 5-25°C, particularly 17-19°C (p.3, lines 28-33, all of p.4, p.5, lines 1-5), for a time period between 1-18 hours, determining a characteristic of the sperm cells, such as a sex characteristic, separating and collecting the sperm cells. WO'906 further teaches transporting the semen from one location to another during the incubation step, the use of an extender (p. 9, lines 1-33, all of p. 10) and antibacterial (Table 1), staining the sperm cells with Hoechst 33342 (p.11, lines 21-28, p. 15, lines 10—18) and separating the sperm cells using a flow cytometer (p.16, lines 1-15, p.18,lines 30-33, example 2, Table 2, Example 3,4,5).

WO'655 teaches a method of separating sperm cells comprising obtaining a semen sample from a male mammal, particularly a bovine or equine mammal (p.2, lines 20-32) incubating the semen sample at temperatures ranging from 5-25°C (p.10, lines 10-25), for a time period between 1-18 hours, determining a characteristic of the sperm cells, such as a sex characteristic, separating and collecting the sperm cells. WO '655 further teaches transporting the semen from one location to another during the incubation step (p.3), the use of an extender (p.7) and antibiotics (p.9, liens 25-33, Example 1), staining the sperm cells with Hoechst 33342 (Example 2,3) and separating the sperm cells using a flow cytometer (examples 2, 3).

The above references do not teach staining for a period of 30 minutes

Tardif teaches staining sperm cells with Hoechst 33342 for a period of 30 minutes (p. 202, Experiment 1, 2, Results section).

Johnson teaches a method of separating sperm cells comprising a flow cytometry method including staining sperm cells with Hoechst 33342 for less than or equal to 1 hour. They also teach the use of an extender (p. 900, Preparation of sperm for sorting viable sperm by flow cytomtery section).

Seidel teach a method of separating sperm cells comprising incubating semen at temperatues above liquid to gel phase transition, staining with Hoechst 33342 for a period of 45 minutes, separating and collecting said separated sperm cells (see p.736, Box 1, p.736, whole page, p. 734, DNA-binding dye section).

The above references do not teach adding caffeine to semen.

Ellington teaches the addition of caffeine to semen (col. 5, lines 44-46).

The references do not teach the specific extenders KMT. However, they do teach that proper extenders are well known to those skilled in the art and therefore one of skill in the art would choose a proper extender depending on the mammal. KMT and INRA extenders are known in the art to be proper equine extenders, as supported by Padilla, who teach the use of KMT and INRA extenders for stallion semen at about 5°C.

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art the use a proper semen extender known in the art depending on the mammal.

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to have stained sperm cells with Hoechst 33342 for a period of 30 minutes with a reasonable expectation for successfully maintaining sperm motility because Tardif teaches that staining for a period of 30 minutes does not depress sperm motility. Further it would have been obvious to add caffeine to a semen sample as caffeine is well known in the art to be a sperm stimulant.

Further, adjusting the staining time period, dye concentration and amount of sperm cells stained would be well within the purview of one of ordinary skill in the art at the time of the invention as a mere optimization of a result effective variable. *Support is provided by Johnson and Seidel who clearly teach that staining with Hoechst 33342 for less than 1 hour is successful in a sperm cell separating method.* Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the

prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). See MPEP 2144.05.

Claims 1, 5-12, 15, 16, 18, 21, 150, 154 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of WO 02/41906 A2 and WO 01/37655 A1 in view of Tardif et al. (Journal of Andrology, 1998) in further view of each of WO 02/28311 A1and Lindsey et al (ARS, 2001) supported by Johnson (Reprod. Fert. Dev., 1995) and Seidel et al., (Reproduction, 2002).

WO'906 teaches a method of separating sperm cells comprising obtaining a semen sample from a male mammal, particularly a bovine or equine mammal (p.9, lines 11-18), incubating the semen sample at temperatures ranging from 5-25°C, particularly 17-19°C (p.3, lines 28-33, all of p.4, p.5, lines 1-5), for a time period between 1-18 hours, determining a characteristic of the sperm cells, such as a sex characteristic, separating and collecting the sperm cells. WO'906 further teaches transporting the

semen from one location to another during the incubation step, the use of an extender (p. 9, lines 1-33, all of p. 10) and antibacterial (Table 1), staining the sperm cells with Hoechst 33342 (p.11, lines 21-28, p. 15, lines 10—18) and separating the sperm cells using a flow cytometer (p.16, lines 1-15, p.18,lines 30-33, example 2, Table 2, Example 3,4,5).

WO'655 teaches a method of separating sperm cells comprising obtaining a semen sample from a male mammal, particularly a bovine or equine mammal (p.2, lines 20-32) incubating the semen sample at temperatures ranging from 5-25°C (p.10, lines 10-25), for a time period between 1-18 hours, determining a characteristic of the sperm cells, such as a sex characteristic, separating and collecting the sperm cells. WO '655 further teaches transporting the semen from one location to another during the incubation step (p.3), the use of an extender (p.7) and antibiotics (p.9, liens 25-33, Example 1), staining the sperm cells with Hoechst 33342 (Example 2,3) and separating the sperm cells using a flow cytometer (examples 2, 3).

The above references do not teach staining for a period of 30 minutes

Tardif teaches staining sperm cells with Hoechst 33342 for a period of 30 minutes (p. 202, Experiment 1, 2, Results section).

Johnson teaches a method of separating sperm cells comprising a flow cytometry method including staining sperm cells with Hoechst 33342 for less than or equal to 1 hour. They also teach the use of an extender (p. 900, Preparation of sperm for sorting viable sperm by flow cytomtery section).

Seidel teach a method of separating sperm cells comprising incubating semen at temperatues above liquid to gel phase transition, staining with Hoechst 33342 for a period of 45 minutes, separating and collecting said separated sperm cells (see p.736, Box 1, p.736, whole page, p. 734, DNA-binding dye section).

The above references do not teach hysteroscopic insemination.

WO 311 teaches the use of hysterscopic insemination in combination with sex-sorted sperm stained with Hoechst 33342 (p. 10, lines 14-22) as well as increased fertilization rates (p.15, lines 3-20).

Lindsey teach a pregnancy rate of 70-90% for hysterscopic insemination in combination with sex-sorted sperm stained with Hoechst 33342 (p.281, p. 286) as well as a skim-milk glucose extender.

At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to have stained sperm cells with Hoechst 33342 for a period of 30 minutes with a reasonable expectation for successfully maintaining sperm motility because Tardif teaches that staining for a period of 30 minutes does not depress sperm motility. Further it would have been obvious to use hysterscopic insemination because it is disclosed in the art by WO'311 and Lindsey to be an effective insemination method in combination with sex-sorted sperm.

Further, adjusting the staining time period, dye concentration and amount of sperm cells stained would be well within the purview of one of ordinary skill in the art at the time of the invention as a mere optimization of a result effective variable. *Support is provided by Johnson and Seidel who clearly teach that staining with Hoechst 33342 for less than 1 hour is successful in a sperm cell separating method.* Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or

artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). See MPEP 2144.05.

Response to Arguments

Applicant's arguments filed 3/22/21010 have been fully considered but they are not persuasive. In summary, applicant argues that the Tardif reference which was relied upon for the teaching of staining sperm cells for 30 minutes with Hoechst 33342, does not teach separating the sperm cells into X and Y chromosome bearing populations. Applicant argues that WO'655 does not teach a temperature above the transition temperature. It appears as if applicant argues that the Johnson reference does not teach the staining time required in the claims.

It is the examiner's position that it is well known to one of ordinary skill in the art to use Hoechst 33342 for sperm sorting methods because Hoechst is well known to be non-toxic to sperm and is useful in assessing precise amounts of DNA in cells (see Seidel DNA-binding dyes section, p. 734). Hoechst has been used in the art for years, see art of record. WO'655 teaches staining at 34°C for 60 minutes, the same as that exemplified in applicants specification. Tardif was relied upon to teach that a staining period of 30 minutes is sufficient to stain sperm cells and not effect viability of sperm cells. Tardif also teach that Hoechst 33342 is useful in flow cytometry methods because the dye does not render the sperm cells infertile and has produced healthy

calves. In addition they teach that fertility of sperm used for artificial insemination following staining with Hoechst 33342 was not affected (see p. 205, Discussion section, 2nd paragraph). Thus, applicants argument stating, "One skilled in the art would understand from reading this article that the stain experiments and tests would not be applicable to separating parameters for sperm cells as this reference does not mention separation at all" is **not persuasive**. Further, both Johnson and Seidel teach staining sperm cells with Hoechst 33342 for time periods of less than 1 hour in a separation method. Johnson clearly states sperm are incubated at 32-35°C for less than 1 hour. Johnson clearly teaches the claim limitation. Thus, Johnson and Seidel as well as the other art of record support the Examiners position that staining time and amount is mere optimization of a result effective variable. Therefore, applicants argument that the invention of claim 1 yields unexpected results not present in the prior art is not persuasive. The claimed method is well-known in the art.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

/Tiffany M Gough/
Examiner, Art Unit 1657